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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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In re: ZYPREXA PRODUCTS LIABILITY
LITIGATION

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MICHAEL SINGER, AND PAULA
SINGER, AS PARENTS AND
NATURAL GUARDIANS OF
MICHAEL L. SINGER II,

Plaintiffs,

-against-

ELI LILLY & COMPANY,

Defendant.

-----x
Jack B. Weinstein, Senior United States District Judge:

MEMORANDUM, ORDER ~~BY~~ **BROOKLYN OFFICE**
& JUDGMENT

04-MD-1596 (JBW)

06-CV-1338 (JBW)

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I. Introduction

Defendant Eli Lilly & Company (“Lilly”) moves for summary judgment against Michael L. Singer II (“claimant”), a juvenile whose parents bring this cause of action on his behalf. The action was commenced against Lilly on January 19, 2006, in the Middle District of Pennsylvania. Plaintiffs and claimant reside in Pennsylvania. The case was transferred to the Eastern District of New York pursuant to an order of the Judicial Panel on Multidistrict Litigation.

It is alleged by plaintiffs that: 1) Zyprexa, a drug produced by Lilly, an Indiana corporation, caused claimant’s diabetes; 2) Lilly failed to warn of the dangers of Zyprexa; and 3) Zyprexa would not have been prescribed, and diabetes would not have been suffered, if proper warnings had been given. In its motion for summary judgment, Lilly contends that the warning plaintiffs state should have been given would not have prevented or changed the prescription of Zyprexa in claimant’s case.

For the reasons stated below, defendant’s motion for summary judgment is granted.

II. History of Zyprexa Litigation

This massive and highly complex multidistrict litigation has included claims brought by individual Zyprexa users, states, third-party payors, and other entities alleging physical or financial injury. Some 30,000 cases have been brought against Lilly by individual plaintiffs suffering from serious psychiatric problems who were treated with the Lilly antipsychotic drug Zyprexa. They principally allege that Zyprexa caused deleterious side effects of excessive weight gain, hyperglycemia, and diabetes; that Lilly misled them and their physicians about the likelihood of these side effects; and that, had they or their attending physicians been aware of the risk, they would not have taken Zyprexa.

Litigation against Lilly for injuries allegedly caused by Zyprexa was initiated in this court in March 2004. *See Benjamin v. Eli Lilly & Co.*, No. 04-CV-893. Thousands of cases were then transferred here from federal district courts throughout the United States pursuant to an order of the Judicial Panel on Multidistrict Litigation. *See Letter from Multidistrict Litigation Panel to Clerk of the Eastern District of New York*, No. 04-MD-1596, Docket Entry No. 1, Apr. 14, 2004. Similar cases have been litigated in state courts. *See In re Zyprexa Prods. Liab. Litig.*, 239 F.R.D. 316 (E.D.N.Y. 2007) (“Memorandum on Cooperation Between Federal and State Judges”).

The individual Zyprexa user litigation has been administered as a quasi-class action. *See In re Zyprexa Prods. Liab. Litig.*, 467 F. Supp. 2d 256, 262 (E.D.N.Y. 2006) (“The court, magistrate judge and special masters will continue to administer this litigation as a quasi-class action.”); *In re Zyprexa Prods. Liab. Litig.*, 451 F. Supp. 2d 458, 477 (E.D.N.Y. 2006) (“Recognizing its obligation to exercise careful oversight of this national ‘quasi-class action,’ the court has already utilized its equitable power to limit attorneys’ fees and costs.”) (citation

omitted); *In re Zyprexa Prods. Liab. Litig.*, 433 F. Supp. 2d 268, 271 (E.D.N.Y. 2006) (finding that individual Zyprexa user litigation “may be characterized properly as a quasi-class action subject to the general equitable power of the court”); *In re Zyprexa Prods. Liab. Litig.*, 424 F. Supp. 2d 488, 491 (E.D.N.Y. 2006) (same); *In re Zyprexa Prods. Liab. Litig.*, 233 F.R.D. 122, 122 (E.D.N.Y. 2006) (same).

Cooperation between federal and state courts has been encouraged at all stages of the Zyprexa litigation. *See, e.g., In re Zyprexa Prods. Liab. Litig.*, 467 F. Supp. 2d 256, 262 (E.D.N.Y. 2006) (“Cooperation with state courts will continue to be stressed.”); *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2006 WL 898105, at *1 (E.D.N.Y. Apr. 16, 2006) (“Coordination and cooperation between state and federal courts has been encouraged.”); *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2006 WL 197151 (E.D.N.Y. Jan. 30, 2006) (letter to state judges with Zyprexa cases suggesting coordination and cooperation); *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2004 WL 3520248, at *4 (E.D.N.Y. Aug. 18, 2004) (directing defendant Lilly and Plaintiff’s Steering Committee I to “confer regarding procedures for coordination of state court discovery with discovery in this MDL”).

A national system for resolving Medicare and Medicaid liens was approved. *See In re Zyprexa Prods. Liab. Litig.*, 451 F. Supp. 2d 458 (E.D.N.Y. 2006). All states and the federal government agreed to modify their lien demands to provide a national equitable system. *See In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2006 WL 3501263, at *1 (E.D.N.Y. Dec. 4, 2006) (“In compliance with this court’s instructions . . . all fifty states as well as the federal government have resolved their Medicare and Medicaid liens.”) (citation omitted).

On April 16, 2004, a class action was filed on behalf of individuals claiming personal injury based on, among other claims, Lilly's failure to provide an adequate warning about the risks of Zyprexa. *See Ortiz v. Eli Lilly & Company*, No. 04-CV-1587 (E.D.N.Y.). A second and substantially similar class action was filed in this court on May 19, 2004. *See Tringali v. Eli Lilly & Company*, No. 04-CV-2104 (E.D.N.Y.). On September 15, 2004, Lilly and plaintiffs' counsel in the two putative class actions entered an agreement to execute stipulations of dismissal of the class actions, with the effective date of dismissal to be November 1, 2004, 167 days after the *Ortiz* action was filed. *See Joint Memorandum of the Parties Regarding Stipulation of Voluntary Dismissal of Certain Claims*, No. 04-MD-1596, Docket Entry No. 80, Attach. 2.

Discovery and negotiations were overseen in part by a court-appointed special discovery master and four special settlement masters. In November 2005 Lilly, without conceding liability, entered into a settlement covering some 8,000 individual plaintiffs. *See In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2005 WL 3117302 (E.D.N.Y. Nov. 22, 2005). The settlement resolved virtually all cases then pending in the MDL, along with some state cases. *See id.*

An attorneys' fee structure for many cases was ordered, capping fees at 20% of recovery in smaller, lump-sum claims, and at 35% of recovery in other claims. *See In re Zyprexa Prods. Liab. Litig.*, 424 F. Supp. 2d 488 (E.D.N.Y. 2006). Costs related to the individual cases and charged to the individual settling plaintiffs were limited. *See In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2006 WL 2443248 (E.D.N.Y. Aug. 24, 2006). Counsel for some 2,000 individual plaintiffs filed an appeal of an order capping fees, *see In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2007 WL 2340789 (E.D.N.Y. Aug. 17, 2007), which is now pending

before the Court of Appeals for the Second Circuit. The magistrate judge allocated funds from a first common benefit fund after reviewing the first Plaintiffs' Steering Committee's ("PSC I") applications. *See In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2007 WL 805793 (E.D.N.Y. Mar. 15, 2007). Allocation of funds has been substantially completed for PSC I.

Following an influx of thousands of new cases, in January 2007 the parties announced another round of settlements, which are nearing completion. A second common benefit fund was established to compensate members of a second PSC for their work. *See In re Zyprexa Prods. Liab. Litig.*, 467 F. Supp. 2d 256, 262 (E.D.N.Y. 2006).

Four motions for summary judgment by Lilly in individual *Zyprexa* cases were decided in June 2007. Three of those motions were denied and one was granted based on application of the statute of limitations, which barred that plaintiff's claim. *See Souther, et al. v. Eli Lilly & Co.*, 489 F. Supp. 2d 230 (E.D.N.Y. 2007).

A class action has been brought on behalf of third-party payor institutional plaintiffs that include pension funds, labor unions, and insurance companies that cover their members' health benefits; they have covered payments for Zyprexa prescriptions. Mail fraud under the Racketeer Influenced and Corrupt Organizations Act ("RICO") is alleged, *see* 18 U.S.C. § 1964, predicated on overpricing supported by excessive claims of utility as well as disavowal of adverse secondary effects of the drug, primarily weight gain and diabetes. That class has been certified. *See In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. 69, 201 (E.D.N.Y. 2008). Individual plaintiffs who bought, or paid a portion of the purchase price for, Zyprexa for their own use also sought class action status on a similar theory. Certification of this individual payor class action was denied. *See id.* at 201-02.

Many state attorneys general have sued on behalf of their states' citizens seeking reimbursement for overpayments for Zyprexa made with state and federal funds via state Medicaid programs and other remedies based upon state law grounds. Currently pending in this court are actions on behalf of the citizens of nine states. A putative *qui tam* action by a whistleblower representing California was dismissed. Order, *California ex rel. Jaydeen Vincente v. Eli Lilly & Co.*, Apr. 23, 2008, No. 08-CV-600, Docket Entry No. 84. The case originating in this district, brought by the state of Connecticut, will be tried on November 9, 2009 if it has not been settled or dismissed before that date. See Order, Apr. 21, 2009, No. 08-CV-955, Docket Entry No. 205. Motions for summary judgment in other state attorney general cases before this court will be heard in fall 2009. See Case Management Order No. 6, No. 04-MD-1596, Docket Entry No. 2092, Mar. 13, 2009.

In March 2008, Lilly reportedly settled with the state of Alaska during trial in a related case. See Alex Berenson, *Alaska Suit Against Lilly Is Settled*, N.Y. Times, Mar. 26, 2008, at C1 (reporting the settlement agreement reached after three weeks of trial before the case went to the jury). That state's lawsuit sought reimbursement for the medical costs of Alaska Medicaid patients who developed diabetes while taking Zyprexa; the state's claim to recover costs associated with Lilly's off-label promotion of Zyprexa was dismissed before trial. See Alex Berenson, *Lilly Executive Discussed Off-Label Uses for Drug*, N.Y. Times, Mar. 15, 2008, at C1. Some of the materials introduced in that trial are available as part of the public record. Other Zyprexa settlements have followed. See Alex Berenson, *33 States to Get \$62 Million in Zyprexa Case Settlement*, N.Y. Times, Oct. 7, 2008, at B7.

Some of Lilly's shareholders have filed suit because of the decline in share price. *See In re Eli Lilly & Co. Securities Litig.*, No. 07-CV-1310 (E.D.N.Y.). This litigation has been dismissed on statute of limitations grounds. *See In re Zyprexa Prods. Liab. Litig.*, 549 F. Supp. 2d 496 (E.D.N.Y. 2008).

Current shareholders have sued in this court in the form of three separate shareholder derivative actions. *See Waldman v. Taurel*, No. 08-CV-560 (E.D.N.Y.); *City of Taylor Employees Retirement System v. Taurel*, No. 08-CV-1554 (E.D.N.Y.); *Robins v. Taurel*, No. 08-CV-1471 (E.D.N.Y.). Similar cases are pending in other courts. Settlement negotiations are ongoing.

Additional cases transferred to the multidistrict litigation are being managed by a special master, who is tracking settlements, setting timelines for discovery and the adjudication of dispositive motions, and scheduling trial dates. *See Case Management Order No. 32*, 04-MD-1596, Docket Entry No. 2072, Mar. 3, 2009. Several cases originally set for trial have been settled or withdrawn. Individual actions originating in the Eastern District of New York have been placed on an expedited discovery and motion schedule so that trial on those actions may, if necessary, move forward without undue delay.

A series of summary judgment motions by Lilly in individual Zyprexa user actions are now pending. The court has ruled on the parties' *Daubert* motions challenging proposed expert testimony in a number of these and other cases. *See Mem. & Order*, 04-MD-1596, Docket Entry No. 2170, May 12, 2009 (ordering the exclusion of plaintiff's proposed expert testimony in twenty cases); *see also Mem. & Order*, 04-MD-1596, Docket Entry No. 2169, May 12, 2009 (approving plaintiffs' proposed expert testimony in two cases); *Mem. & Order*, 04-MD-1596,

Docket Entry No. 2171, May 12, 2009 (approving defendant's proposed expert testimony); *Souther*, 489 F. Supp. 2d at 281-91 (denying plaintiffs' and defendant's *Daubert* motions to exclude expert testimony).

III. Facts

A. Contents and Use of Zyprexa

Zyprexa's active ingredient is olanzapine, one of a class of medications known as "atypical" or "second generation" antipsychotics. It was approved for use in treating schizophrenia and acute manic episodes associated with bipolar disorder by the United States Food and Drug Administration ("FDA") in 1996. In 2004, the FDA also approved Zyprexa for the treatment of bipolar disorder generally.

B. Labeling and Warnings to Patients and Medical Professionals

1. *FDA Labeling and "Dear Doctor Letter"*

The 1996 Zyprexa package insert accompanying the drug disclosed information about possible side effects of administration of olanzapine based on clinical trials. The information was provided, in part, the following information:

Adverse Events Occurring at an Incidence of 1% or More Among Olanzapine-Treated Patients in Short-Term, Placebo-Controlled Trials - - [The tables] enumerate[] the incidence, rounded to the nearest percent, of treatment-emergent adverse events that occurred during acute therapy (up to 6 weeks) of schizophrenia in 1% or more of patients treated with olanzapine (doses \geq 2.5 mg./day) where the incidence in patients treated with olanzapine as greater than the incidence in placebo-treated patients. The prescriber should be aware that the figures in the tables and tabulations cannot be used to predict the incidence of side effects in the course of usual medical practice where patient characteristics and other factors differ from those that prevailed in the clinical trials. Similarly, the cited frequencies cannot be compared with figures obtained from other clinical investigations

involving different treatments, uses, and investigators. The cited figures, however, do provide the prescribing physician with some basis for estimating the relative contribution of drug and nondrug factors to the side effect incidence in the population studies.

Zyprexa Package Insert, dated October 1, 1996, at 11 (emphasis in original).

Two tables in the insert provide the results of placebo-controlled clinical studies of olanzapine-treated patients. The data indicates that, over a six-week administration of Zyprexa, six percent of olanzapine-treated patients reported weight gain, while only one percent of the placebo-treated patients reported weight gain. *Id.* at 12-16.

For several years, this information on the insert remained substantially the same insofar as it provided physicians information on reported weight gain-related adverse events. During this period, the results of longer-term studies and clinical experience with Zyprexa and competing drugs became widely known. *See* Part III.B.IV, *infra*.

In May 2000, the FDA undertook an analysis of the incidence of diabetes and hyperglycemia in patients using atypical antipsychotics. The director of the FDA's Division of Neuropharmacological Drug Products ("DNPD") requested additional safety information about Zyprexa from Lilly. In its letter, the FDA cited post-marketing reports of diabetes-related adverse events associated with Zyprexa use. In response, Lilly provided the FDA with clinical studies, data analysis, and case report reviews. The parties disagree about whether the information given by Lilly to the FDA was complete and accurate.

On September 11, 2003, the FDA announced it would require a warning about risks of hyperglycemia and diabetes mellitus and treating precautions to appear in the package insert of all atypical antipsychotics, including Zyprexa. Designed for prescribing doctors, the label noted

that epidemiological studies and other information indicated that the relationship between the drug and hyperglycemia and diabetes was not yet fully understood. It reads as follows:

WARNINGS

Hyperglycemia and Diabetes Mellitus

Hyperglycemia, in some cases extreme and associated with ketoacidosis or hypersomolar coma or death has been reported in patients treated with atypical antipsychotics including Zyprexa. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics studied. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available

Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing.

The label did not mention weight gain or diabetes in the “warning to patients” section.

Lilly added the FDA-required language to the Zyprexa label on September 16, 2003. It issued a press release announcing the label change on September 17, 2003. At the FDA’s request, on March 1, 2004, Lilly sent a “Dear Doctor” letter to physicians in the United States informing them of the 2003 label change.

2. *Consensus Statement of American Diabetes Association and Other Learned Groups*

In November 2003, the American Diabetes Association, American Psychiatric Association, American College of Clinical Endocrinologists, and the North American Association for the Study of Obesity convened a consensus development conference (the “ADA consensus conference”) on the subject of the association between antipsychotic drugs and diabetes. An eight-member panel heard presentations from fourteen experts drawn from the fields of psychiatry, obesity, and diabetes; FDA representatives; and atypical antipsychotic drug manufacturers. The panel reviewed most of the relevant peer-reviewed English language scientific articles.

The ADA consensus conference concluded that Zyprexa and Clozaril posed an increased risk of diabetes as compared to other atypical antipsychotic drugs. The consensus statement produced by the conference declared that these relative risks as well as advantages of the individual drugs for individual patients in a heterogeneous population “should . . . influence drug choice.” In part, its report concluded:

There is considerable evidence, particularly in patients with schizophrenia, that treatment with [atypical antipsychotics] can cause a rapid increase in body weight in the first few months of therapy that may not reach a plateau even after 1 year of treatment. There is, however, considerable variability in weight gain among the various [atypical antipsychotics] . . . Clozapine [Clozaril] and olanzapine [Zyprexa] . . . produce the greatest weight gain.

Despite limitations in study design, the data consistently show an increased risk for diabetes in patients treated with clozapine [Clozaril] or olanzapine [Zyprexa] compared with patients not receiving treatment with [first generation antipsychotics] or with

other [atypical antipsychotics]. The risk in patients taking risperidone and quetiapine is less clear; some studies show an increased risk for diabetes, while others do not. The two most recently approved [atypical antipsychotics], aripiprazole and ziprasidone, have relatively limited epidemiological data, but available clinical trial experience with these drugs has not shown an increased risk for diabetes.

[T]he risks of obesity, diabetes, and dyslipidemia have considerable clinical implications in this patient population and should . . . influence drug choice. Even for those medications associated with an increased risk of metabolic side effects, the benefit to specific patients could outweigh the potential risks. For example, clozapine [Clozaril] has unique benefits for treatment-refractory patients and those at significant risk for suicidal behavior. Since treatment response in many psychiatric conditions is heterogeneous and unpredictable, physicians and patients can benefit from the availability of a broad array of different therapeutic agents.

These three adverse conditions [obesity, diabetes, and dyslipidemia] are closely linked, and their prevalence appears to differ depending on the [atypical antipsychotic] used. Clozapine [Clozaril] and olanzapine [Zyprexa] are associated with the greatest weight gain and highest occurrence of diabetes and dyslipidemia. Risperidone and quetiapine appear to have intermediate effects. Aripiprazole and ziprasidone are associated with little or no significant weight gain, diabetes, or dyslipidemia, although they have not been used as extensively as other agents. The choice of [atypical antipsychotic] for a specific patient depends on many factors. The likelihood of developing severe metabolic disease should also be an important consideration.

3. FDA March 2007 Letter

On March 28, 2007, the FDA raised concerns about the adequacy of Zyprexa's warning label in a letter to Lilly.

[W]e are concerned that the labeling is deficient with regard to information about weight gain, hyperglycemia, and hyperlipidemia that is associated with olanzapine [Zyprexa] use Our overall goal is to improve labeling with regard to these findings so that clinicians will be better informed on what the risks are for their patients. They cannot make reasonable treatment decisions until they have such information. We do not feel that current labeling for . . . Zyprexa provides sufficient information on these risks, and we fully intend to insure that . . . labels are enhanced with the best available information to characterize these risks.

4. Findings on Medical Community's Knowledge of Zyprexa's Risks

A universally applicable date from which the statute of limitations is to be considered to run on an individual Zyprexa user's claim has not been determined. Numerous events represent moments at which a patient, health care provider, institution, or the medical community at large arguably discovered that the cause of an alleged injury may have been the administration of Zyprexa. The evidence in this mass litigation, including medical records and the depositions of numerous doctors, suggests that it was widely known and understood in the late 1990s among treating and prescribing physicians that weight gain may follow the administration of Zyprexa. The association between weight gain and heightened risks of diabetes was also broadly recognized by that time.

Formal events include the September 2003 Zyprexa label change and contemporaneous press release, the 2003 consensus statement of the American Diabetes Association, and the March 2004 "Dear Doctor" letter distributed nationwide to physicians by Lilly.

In its June 2007 memorandum, order, and judgment on the four motions for summary judgment, this court found that the March 2004 "Dear Doctor" letter would be considered the latest possible date on which members of the medical community knew or should have known about Zyprexa's obesity- and diabetes-related risks to patient health. *See Souther*, 489 F. Supp.

2d at 278. In *Souther*, applying the relevant “learned intermediary” doctrine, it was determined that one plaintiff was barred by the statute of limitations:

Diabetes developed and Zyprexa was prescribed [to plaintiff Cusella] years before the September 2003 label change. *At least from the date of March 2004 Dear Doctor letter, the causal connection between Zyprexa and diabetes was known to Dr. Ganime, Cusella’s treating physician.* Since Lilly’s duty to warn ran to Dr. Ganime rather than Cusella, it became Dr. Ganime’s duty from that point onwards to disclose to Cusella that Zyprexa might exacerbate his diabetes, and that it may have been the impetus behind Cusella’s insulin-dependancy in the first place.

Dr. Ganime’s medical records and deposition testimony . . . show that Cusella was warned numerous times about the link between Zyprexa and diabetes. While the pre-label change warnings Dr. Ganime received from Lilly *may* not have been adequate to absolve Lilly of liability to Cusella, those warnings Cusella received from Dr. Ganime following the label change placed him on notice that use of Zyprexa might have worsened his diabetes and caused him to become insulin-dependent.

Measured either against the date Cusella developed diabetes — August 1999 — or the latest possible date Dr. Ganime was aware of the potential causal connection between Zyprexa and diabetes — March 2004 — Pennsylvania’s two year statute of limitations had run on Cusella’s claim before he filed this suit in April of 2006.

Id. at 278 (emphasis added).

The March 1, 2004 date represents the “latest possible date” which prescribing physicians and, in effect, their patients are deemed aware of the potential causal connection between Zyprexa and diabetes and from which the statute of limitations may run as to any individual plaintiff. Nevertheless, a fact-specific analysis is necessary for each case to determine when the plaintiff – whether independently or by operation of the learned intermediary doctrine, *see* Part IV.C, *infra* – knew the potential causal connection between Zyprexa and adverse health effects.

The facts in many individual cases indicate a much earlier date of discovery for purposes of the statute of limitations. *See, e.g.*, Appendices A-D of *Souther*, 489 F. Supp. 2d 230 (including over 1500 pages of relevant depositions demonstrating doctors' awareness of Zyprexa's association with patient weight gain).

C. Michael L. Singer II: Medical History and Parents' and Treating Physician's Knowledge of Zyprexa Risks

1. *Claimant's Medical History*

Claimant is now nineteen years old. He has always lived in Pennsylvania. In May 1999, when claimant was nine years old, Dr. Glenn Stayer, claimant's Pennsylvania-based pediatrician, concluded that he had Tourette's disorder, obsessive-compulsive disorder, impulse control disorder, mood disorder, and developmental disorder. Def. Statement of Undisputed Material Facts (hereinafter "Def. SUF"), Ex. 5, SINGERM_STAYERG_0009-11. A neurologist had previously noted that the claimant exhibited "prominent" tics and a "long [history] of being somewhat hyperactive" and demonstrated "semi-involuntary motor activity." *Id.*, Ex. 5, SINGERM_STAYERG_0009-11; Ex. 6, SINGERM_PECKW_0078-79. As a result of these clearly observable medical problems, the claimant's social life and the burden on his parents were staggering. He avoided socializing with peers because of his tics. His neurological conditions posed considerable challenges for him at school. *Id.*, Ex. 5, SINGERM_STAYERG_0009-11. His parents attempted to cope by seeking and participating in medical treatment for their son.

Upon his initial psychiatric diagnoses in May 1999, claimant was started on 10 mg of Prozac. *Id.* In July 1999, Dr. Stayer increased the Prozac dose to 20 mg because claimant had

shown little improvement in school. *Id.*, Ex. 5, SINGERM_STAYERG_0014. In October 1999, Risperdal, a second generation antipsychotic drug, was added to the treatment regimen. *Id.*, Ex. 5, SINGERM_STAYERG_0018. Over the next nine months, there were initial indications of “marked improvement . . . in [claimant’s] academic skills [and] OCD symptoms, decrease in aggression and improving social skills.” *Id.*, Ex. 5, SINGERM_STAYERG_0020-21. Indications of the treatment’s effectiveness then diminished, with documented side effects of the medications including considerable weight gain and sedation; on June 1, 2000, claimant weighed approximately 86 pounds and was 4’5” tall. *Id.* This weight was a considerable increase from a measurement taken at a medical examination about one year earlier, when claimant’s weight was approximately 72 pounds. *Id.*, Ex. 5, SINGERM_STAYERG_0009-11.

Dr. Stayer decided to wean claimant off Risperdal and replace it with Zyprexa. *Id.*, Ex. 6, SINGERM_PECKW_0118; Ex. 5, SINGERM_STAYERG_0024-25. On December 1, 2000, claimant initiated treatment on Zyprexa, which would continue for slightly more than one year. *Id.*, Ex. 5, SINGERM_STAYERG_0024-34. His weight was 97 ½ pounds when Zyprexa treatment began. *Id.*

In July 2001, Dr. William Peck noted that claimant’s weight gain “was persisting on Prozac and Zyprexa,” claimant’s weight having increased to 116 pounds. *Id.* Dr. Peck, together with claimant and his parents reviewed the side effects of the two drugs. Based on claimant’s continued struggles with Tourette’s disorder, obsessive-compulsive disorder, mood disorder, and developmental disorder, the decision was made to increase use of Zyprexa. Approximately six months later, on January 25, 2002, claimant told his doctor that he was “very concerned about possible effects of Zyprexa on weight gain.” Zyprexa was on that date replaced with Orap, a

first-generation antipsychotic medicine. *Id.*, Ex. 5, SINGERM_STAYERG_0033-34; Ex. 2, 38-39. Claimant weighed 130 pounds and stood approximately 4'10" tall.

By March 2004, his body weight reached nearly 148 pounds. *Id.*, Ex. 9, SINGERM_STAYERG_0067. On November 11, 2004, almost three years after the discontinuance of Zyprexa, Dr. Peck diagnosed claimant as having diabetes. *Id.*, Ex. 7, SINGERM_FPH_0152. Claimant's weight had dropped considerably since March 2004, a likely result of the onset of diabetes. *Id.*, Ex. 8, SINGERM_SHOEMAKERM_0002.

2. Physician's Knowledge of Zyprexa Risks in Prescribing Decision

Dr. Stayer's prescriptions for the claimant of Risperdal in 1999 and Zyprexa in 2000 were off-label; neither drug carried an indication for use in minors at that time. Pediatricians are authorized to – and often do – prescribe drugs off-label because few medications are tested in and approved specifically for children by the FDA.

When providing atypical antipsychotic medications to any patient, including an off-label prescription to a minor, Dr. Stayer would analyze the possible risks and benefits of administration of the drug. *Id.*, Ex. 2, 33-34. He testified that he discussed the potential side effects of each antipsychotic drug that the claimant was prescribed. *Id.*, Ex. 2, 32, 37. Described during his deposition was Dr. Stayer's knowledge of these side effects and his approach in treating patients with antipsychotic drugs:

Q: Do you understand weight gain to be a known side effect of atypical antipsychotic medications?

A [Dr. Stayer]: Yes.

Q: And have you always known that weight gain was a potential side effect of these types of medications?

A: Yes.

Q: So when prescribing an atypical antipsychotic medication to a patient, you as the prescribing physician make the risk-benefit

analysis and decide that the treatment or the benefit to be had outweighs the risk of the weight gain?

A: Right, while . . . trying to encourage the family to be monitoring it, as well, with their primary care physician and making all efforts to try to control weight.

Id., Ex. 2, 33-34.

He specifically explained the circumstances of claimant's family's decision – made in consultation with Dr. Stayer – to modify antipsychotic medication regimens for claimant:

Q: [In December 2000], you decided at this time to substitute Zyprexa for Risperdal with [claimant's] treatment:

A: That's correct.

Q: And what was your reason for doing so?

A: He'd had significant weight gain on the Risperdal, and we were trying to curb the weight gain.

Q: Okay. Were you also concerned about sedation as an effect of Risperdal?

A: Yes.

Q: And at that time, did you discuss with [claimant] and his family potential side effects of Zyprexa?

A: Yes.

Q: And what were . . . those potential side effects?

A: Sedation, *weight gain can also occur*, mental status change, mood, unacceptable mood changes, and movement disorders.

...

A: *[In July 2001, at a subsequent evaluation,] no clear benefit [was] noted on Zyprexa, and [claimant was] very concerned about possible effects of Zyprexa on weight gain.*

Q: *So [claimant] had expressed to you in the clinic visit that he was concerned about weight gain?*

A: *That's the reason that we switched from Risperdal to Zyprexa, right. This was not a new complaint.*

Q: And was Zyprexa effective in addressing [claimant's] conditions?

A: We tried to keep increasing the medication until we reached a point where we thought that the medication would have been effective and saw a little benefit from it, and eventually switched from Zyprexa to a different medication [Orap].

...

Q: What sort of medicine is Orap?

A: Orap is an antipsychotic medication, as well.

Q: And for what purpose did you prescribe it to [claimant]?

A: To help with his tics.

Q: And did you discuss potential side effects of the Orap medicine with [claimant] and his family?

A: I did.

Q: And what are those potential side effects?

A: Likewise, they can have a movement disorder, tardive dyskinesia; *they can have weight gain*; they can have problems with sedation, problems with mood [], irritability.

Id., Ex. 2, 37-40 (emphasis added).

In an affidavit submitted five and a half months subsequent to Dr. Stayer's deposition of September 30, 2008, as part of plaintiff's response to defendant's instant motion for summary judgment, Dr. Stayer stated: "Had I known, or been advised, at the time I was prescribing Zyprexa to [claimant] that there was a connection between the use of Zyprexa and diabetes, I would have stopped prescribing it and switched him to another drug." Stayer Aff., Mar. 12, 2009.

3. *Chain of Causation: Zyprexa and Development of Diabetes*

Dr. Zachary T. Bloomgarden, a clinical professor in the Division of Endocrinology, Department of Medicine, at the Mount Sinai School of Medicine, with board certification in Internal Medicine and Endocrinology and Metabolism, offered expert testimony on behalf of claimant. He identified "considerable evidence that there is a causal relationship between antipsychotic agents [like Zyprexa] and weight gain" and "considerable evidence that there is a causal relationship between weight gain and the development of diabetes." *Id.*, Ex. 11, 105-06. He noted that claimant gained some seventy-seven pounds between August 21, 1998, and September 11, 2003, with some of that weight gain occurring during the administration of Zyprexa, in the period December 2000 to January 2002. He concluded that there is "reason to

believe that antipsychotic drugs may be causally related to the development of diabetes.” *Id.*, Ex. 11, 108. His testimony indicates that he could not determine whether and to what extent Risperdal, Zyprexa, and Orap, three antipsychotic drugs used by claimant, caused claimant’s diabetic condition. *Id.*, Ex. 11, 150.

IV. Law

A. Summary Judgment Standard

Summary judgment is appropriate only if “there is no genuine issue as to any material fact . . . [in which case] the moving party is entitled to a judgment as a matter of law.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *see also Mitchell v. Washingtonville Central School District*, 190 F.3d 1, 5 (2d Cir. 1999). Summary judgment is warranted when after construing the evidence in the light most favorable to the non-moving party and drawing all reasonable inferences in its favor, there is no genuine issue as to any material fact. Fed. R. Civ. P. 56(c); *see Anderson*, 477 U.S. at 247-50, 255; *Sledge v. Kooi*, 556 F.3d 137, 140 (2d Cir. 2009).

The burden rests on the moving party to demonstrate the absence of a genuine issue of material fact. *Goenaga v. March of Dimes Birth Defects Found.*, 51 F.3d 14, 18 (2d Cir. 1995); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). If the moving party appears to meet this burden, the opposing party must produce evidence that raises a material question of fact to defeat the motion. *See* Fed. R. Civ. P. 56(e). This evidence may not consist of “mere conclusory allegations, speculation or conjecture.” *Cifarelli v. Village of Babylon*, 93 F.3d 47, 51 (2d Cir. 1996); *see also Delaware & Hudson Ry. v. Consolidated Rail Corp.*, 902 F.2d 174, 178 (2d Cir. 1990) (“Conclusory allegations will not suffice to create a genuine issue.”).

B. Choice of Law

Federal courts sitting in diversity jurisdiction apply the forum state's choice of substantive law rules. *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496-97 (1941). If there is an actual conflict as to which body of substantive law applies, this district court, sitting in New York, will apply New York state substantive law. *Booking v. General Star Mgmt. Co.*, 254 F.3d 414, 419-20 (2d Cir. 2001). In general, New York law requires courts to apply the law of the jurisdiction having "the most significant contacts with the matter in dispute." *Auten v. Auten*, 308 N.Y. 155, 160 (N.Y. 1954). *See also Babcock v. Jackson*, 12 N.Y.2d 473, 484 (N.Y. 1963) (emphasizing application of the law of the "jurisdiction which has the strongest interest in the resolution of the particular issue presented" in a tort action). "Where a cause of action accrues outside New York in favor of a nonresident, the foreign statute of limitations is borrowed." *Besser v. E.R. Squibb & Sons, Inc.*, 539 N.Y.S. 2d 734, 737 (N.Y. App. Div. 1989) (internal quotations marks omitted); N.Y. C.P.L.R. § 202 ("An action based upon a cause of action accruing without the state cannot be commenced after the expiration of the time limited by the laws of either the state or the place without the state where the cause of action accrued, except that where the cause of action accrued in favor of a resident of the state the time limited by the laws of the state shall apply.").

C. Pennsylvania Law

Pennsylvania imposes a two-year statute of limitations on negligence claims. *See* 42 Pa. C.S.A. § 5524(7). The present action is essentially a negligence claim seeking money damages for injuries, rather than a fraud or warranty claim demanding reimbursement for money spent for Zyprexa (as plaintiffs in related Zyprexa cases have sought). The Pennsylvania statute of

limitations begins running “as soon as the right to institute and maintain a suit arises; lack of knowledge, mistake or misunderstanding do not toll the running of the statute of limitations.” *Pocono Int’l Raceway v. Pocono Produce, Inc.*, 468 A.2d 468, 471 (Pa. 1983). Pennsylvania’s statute is strictly construed to bar an action unless an applicable exception to the rule acts to toll its running. *Id.*

A “discovery rule” exception to its two-year statute of limitations for negligence actions is recognized by Pennsylvania. Where a plaintiff is unable, despite exercising due diligence, to ascertain his or her injury or its cause, the statute of limitations is tolled until the date when discovery of the cause of action is or should be made. *See Fine v. Checcio*, 870 A.2d 850, 858-59 (Pa. 2005); *Pocono Int’l Raceway*, 468 A.2d at 471; *Ayers v. Morgan*, 154 A.2d 788, 791-92 (Pa. 1959); *see also Calle v. York Hosp.*, 232 F. Supp. 2d 353, 357-58 (M.D. Pa. 2002). The burden is on the party seeking application of the discovery rule to prove inability to gain knowledge of the injury despite the exercise of due diligence. *See Dalrymple v. Brown*, 701 A.2d 164, 167 (Pa. 1997). “The very essence of the discovery rule in Pennsylvania is that it applies only to those situations where the nature of the injury itself is such that no amount of vigilance will enable a plaintiff to detect an injury.” *Id.* at 170; *Pocono Int’l Raceway*, 468 A.2d at 471 (discovery rule designed to protect “blameless ignorance”).

The “learned intermediary” doctrine provides that manufacturers of prescription drugs and medical devices discharge their duty of care to patients by providing adequate warnings to prescribing physicians. Pennsylvania recognizes and applies the learned intermediary doctrine. *See Mazur v. Merck*, 742 F. Supp. 239, 262 (E.D. Pa. 1990); *Makripodis v. Merrell-Dow Pharm., Inc.*, 523 A.2d 374, 378 (Pa. Super. 1987); *Liebowitz v. Ortho Pharm. Co.*, 307 A.2d 449 (Pa.

Super. 1973). Any action involving a prescription drug based upon alleged failure to warn requires that a plaintiff present evidence that a different warning would have caused the prescribing physician to have acted differently. *See Hahn v. Richter*, 673 A.2d 888, 891 (Pa. 1996); *Incollingo v. Ewing*, 282 A.2d 206, 219-20 (Pa. 1971).

A prescribing physician is “expected to make an *independent* medical judgment in determining whether a given drug is appropriate for a particular patient.” *Brecher v. Cutler*, 578 A.2d 481, 485 (emphasis added). The learned intermediary defense is an “aspect of proportionality that shifts at least some of the burden of protecting patients from pharmaceutical manufacturers to treating physicians [T]he learned intermediary rule cannot be viewed as an all-or-nothing regulation that absolves the manufacturer, shifting the onus entirely to the treating physician, but its force in ameliorating liability for damages of the manufacturers cannot be ignored.” *Souther*, 489 F. Supp. 2d at 244. “It is the physician who is in the best position to decide when to use and how and when to inform his patient regarding risks and benefits pertaining to drug therapy.” *Id.* at 265 (quoting Prosser & Keeton on the Law of Torts, 688 (5th ed. 1984)).

V. Application of Law to Facts

A. No Proof of Proximate Causation: Decision to Prescribe Zyprexa

Because Pennsylvania has the most significant contacts with plaintiffs’ claims, the law of that state controls Lilly’s motion for summary judgment. *Auten*, 308 N.Y. at 160.

The present cause of action accrued on the date that Singer was diagnosed with diabetes, November 11, 2004. The complaint was filed on January 17, 2006. Pennsylvania’s two-year statute of limitations does not bar the present claim.

Dr. Stayer testified on numerous occasions that he, claimant, and claimant's family were aware of the risks of weight gain associated with antipsychotic drugs, including Zyprexa. He further explained that he was aware at the time that weight gain is a risk factor for diabetes. There is no indication that a different warning for Zyprexa would have changed the decision made by claimant's physician and family to initiate and continue Zyprexa from December 2000 to January 2002.

Dr. Stayer's subsequent signed statement that, had he known of the connection between the use of Zyprexa and diabetes when he prescribed Zyprexa to claimant, he "would have stopped prescribing it and switched him to another drug," is of no persuasive effect. The affidavit's conclusory legal language is itself ambiguous: the effect of Zyprexa is indirect, since it may cause weight gain, which may in turn cause diabetes. No credit can be given to this post-deposition formal assertion in light of the sworn and uncontradicted testimony, during which both sides had a full opportunity to examine Dr. Stayer under oath. No withdrawal or amendment to the testimony of this physician, made under oath during an extensive deposition, has been offered.

In light of claimant's medical profile and circumstances, the Zyprexa prescription was justified by the terrible problems this child faced in school and at home. Zyprexa was one drug in a series of antipsychotic medicines claimant tried, having consulted with a highly trained and knowledgeable physician who was attentive to his patient's needs and the implications of the available treatment options. Dr. Stayer had ample knowledge of the prospective risks and benefits of Zyprexa, among other medications, and chose to prescribe it in hopes of managing claimant's substantial medical challenges. His decision was an intervening determinative causal

factor between Lilly's allegedly inadequate warning, the use of Zyprexa and plaintiff's weight gain and diabetes. Lilly's alleged failure to warn was not a cause of claimant's weight gain or eventual diabetic condition.

B. No Proof of Proximate Causation: Onset of Diabetes

Though the court need not address the issue of whether plaintiff has established for purposes of summary judgment sufficient support for the contention that Zyprexa use itself was a proximate cause of claimant's diabetic condition, it finds that such factual evidence is lacking. Claimant's expert Dr. Bloomgarden, based on his extensive medical knowledge and review of claimant's records and profile, could only assert a "potential" that claimant's diabetes, diagnosed some thirty-three months after Zyprexa use was terminated, was related to the yearlong administration of the Zyprexa drug. He was unable to determine with any level of scientific probability whether Risperdal, Zyprexa, Orap or some other treatment variable led to claimant's diabetes. The parties agree that there were no documented changes in blood glucose suggesting a diabetic condition prior to the actual diabetes diagnosis on November 11, 2004, approximately three years after Zyprexa use was terminated. *See* Hr'g Tr., May 15, 2009.

C. Motion to Remand

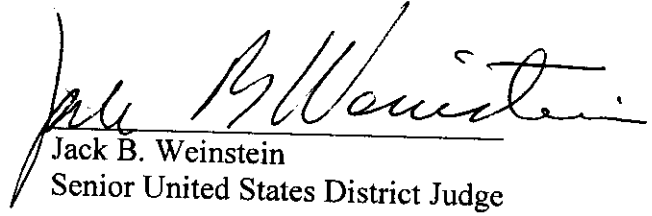
Plaintiff has moved to remand this diversity case to the court of original jurisdiction. Because summary judgment is now granted in defendant's favor, the motion for remand is moot.

VI. Conclusion

The action against Lilly, assessed in the light most favorable to this plaintiff, lacks factual support demonstrating a genuine issue of material fact.

Defendant's motion for summary judgment is granted.

SO ORDERED.



Jack B. Weinstein
Senior United States District Judge

Date: May 15, 2009
Brooklyn, New York